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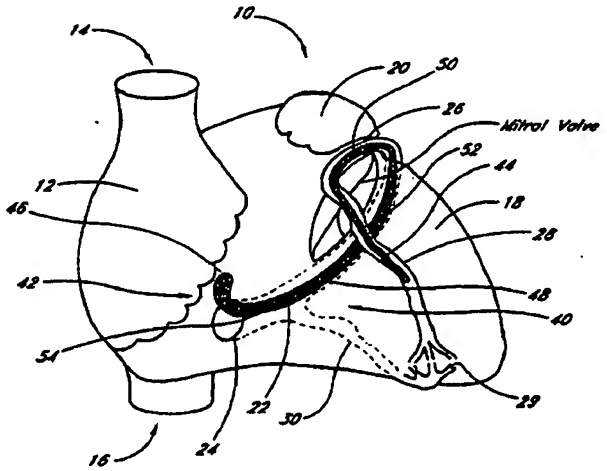
(54) Title: MEDICAL SYSTEM AND METHOD FOR REMODELING AN EXTRAVASCULAR TISSUE STRUCTURE



(57) Abstract: A medical apparatus (40) and method suitable for remodeling a mitral valve annulus adjacent to the coronary sinus (22). The apparatus comprises an elongate body (66) having a proximal region (42) and a distal region (44). Each of the proximal (42) and distal (44) regions is dimensioned to reside completely within the vascular system. The elongate body (66) may be moved from a first configuration for transluminal delivery to at least a portion of the coronary sinus (22) to a second configuration for remodeling the mitral valve annulus proximate the coronary sinus (22). A forming element (56) may be attached to the elongate body (66) for manipulating the elongate body (66) from the first transluminal configuration to the second remodeling configuration. Further, the elongate body (320) may comprise a tube (325) having a plurality of transverse slots (330) therein.

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MEDICAL SYSTEM AND METHOD FOR REMODELING AN EXTRAVASCULAR TISSUE STRUCTURE

Background of the Invention

Field of the Invention

The present invention relates to intravascular prostheses for remodeling an extravascular anatomical structure. In one application, the present invention relates to a mitral annuloplasty and cardiac reinforcement device which is transluminally implantable in the coronary sinus.

Description of the Related Art

Dilated cardiomyopathy occurs as a consequence of many different disease processes that impair myocardial function, such as coronary artery disease and hypertension. The left ventricle enlarges and the ejection fraction is reduced. The resulting increase in pulmonary venous pressure and reduction in cardiac output cause congestive heart failure. Enlargement of the mitral annulus and left ventricular cavity produce mitral valvular insufficiency. This in turn, causes volume overload that exacerbates the myopathy, leading to a vicious cycle of progressive enlargement and worsening mitral regurgitation.

According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques have been developed to repair a diseased or damaged valve. One repair technique which has been shown to be effective in treating incompetence, particularly of the mitral and tricuspid valves, is annuloplasty, in which the effective size of the valve annulus is contracted by attaching a prosthetic annuloplasty ring to the endocardial surface of the heart around the valve annulus. The annuloplasty ring comprises an inner substrate of a metal such as stainless steel or titanium, or a flexible material such as silicone rubber or Dacron cordage, covered with a biocompatible fabric or cloth to allow the ring to be sutured to the heart tissue. The annuloplasty ring may be stiff or flexible, may be split or continuous, and may have a variety of shapes, including circular, D-shaped, C-shaped, or kidney-shaped. Examples are seen in U.S. Pat. Nos. 4,917,698, 5,061,277, 5,290,300, 5,350,420, 5,104,407, 5,064,431, 5,201,880, and 5,041,130, which are incorporated herein by reference.

Annuloplasty rings may also be utilized in combination with other repair techniques such as resection, in which a portion of a valve leaflet is excised, the remaining portions of the leaflet are sewn back together, and a prosthetic annuloplasty ring is then attached to the valve annulus to maintain the contracted size of the valve. Other valve repair techniques in current use include commissurotomy (cutting the valve commissures to separate fused valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of the valve leaflets or annulus.

arteries to induce cardioplegia, manipulation of surgical instruments, removal of excised tissue, and introduction of an annuloplasty ring or a replacement valve through atriotomy for attachment within the heart.

Mitral valve surgery, including mitral annuloplasty, is usually applied to patients with intrinsic disease of the mitral apparatus. As described, above, these patients may have scarring, retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus. Definitive repair requires direct visualization of the valve.

Patients who develop mitral regurgitation as a result of dilated cardiomyopathy do not have intrinsic mitral valve disease. Regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. The ventricle enlarges and becomes spherical, pulling the papillary muscles and chordae away from the plane of the valve and further enlarging the regurgitant orifice. In these patients, correction of the regurgitation does not require repair of the valve leaflets themselves, but simply a reduction in the size of the annulus and the sphericity of the left ventricle.

Mitral annuloplasty without repair of the leaflets or chordae has been shown to be effective in patients with dilated cardiomyopathy who are refractory to conventional medical therapy. Bolling and coworkers have operated on a cohort of such patients with New York Heart Association Class III and IV symptoms. Average symptom severity decreased from 3.9 preoperatively to 2.0 after surgery. Hemodynamics and ejection fraction improved significantly. Other investigators have achieved similar results as well. However, the morbidity, risks and expense of surgical annuloplasty are very high in patients with cardiomyopathy and congestive heart failure. Thus, a variety of new techniques for the treatment of congestive heart failure are being explored as adjuncts to drug therapy.

Several cardiac restraint devices have been described. U.S. Patent No. 5,702,343 to Alferness discloses a cardiac reinforcement device that is applied as a jacket over the epicardium in order to limit diastolic expansion. However, this requires an open chest operation to implant and does not directly affect the diameter of the mitral annulus. Another approach is disclosed in U.S. Patent No. 5,961,440 to Schweich, et al., in which tension members are placed through opposite walls of the heart such that they span the ventricle. Less invasive and "minimally" invasive techniques for valve repair and replacement continue to evolve, both on a stopped heart and on a beating heart. These techniques may provide some benefits over open chest procedures, but they are still attended by significant morbidity and mortality risks.

A need therefore remains for methods and devices for treating mitral valvular insufficiency, which are attended by significantly lower morbidity and mortality rates than are the current techniques, and therefore would be well suited to treat patients with dilated cardiomyopathy. Optimally, the procedure can be accomplished through a percutaneous, transluminal approach, using simple, implantable devices which do not depend upon prosthetic valve leaflets or other moving parts.

Summary of the Invention

In accordance with one aspect of the present invention, there is provided a medical apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus. The medical apparatus desirably includes an

third zone. The control elements may be pull or push wires or rotatable rods or tubes depending upon the flexing or locking mechanism. Retention structures are provided on the implant, for restraining the implant in the curved configuration, within the body of a patient.

In accordance with a further aspect of the present invention, there is provided a deflectable implant. The implant comprises an elongate flexible housing having proximal and distal ends and a central lumen extending therebetween. The housing is flexible in a lateral direction. An axially extending column strength support is provided in the implant. At least a first deflection wire having proximal and distal ends extends along the housing, said wire being secured at a first point of attachment with respect to distal portion of the column strength support. A lock is provided at the proximal end of the housing, for engaging the deflection wire or other component of the device to retain a curve in the housing. The axis of at least a portion of the housing is displaced laterally in response to axial displacement of the deflection wire, thereby causing the distal end of the housing to bend out of the line of the housing longitudinal axis to form a curve in the housing.

In one implementation, the support extends distally to a point within about 2 cm of the distal end of the housing. In one embodiment, the support comprises a portion of the wall of the housing. In an alternate embodiment, the support is distinct from the wall of the housing, and may comprise any of a variety of axially extending column strength supports such as a deflectable metal or polymeric rod or ribbon.

In one embodiment, the deflectable implant comprises a second deflection wire, secured at a second point of attachment in-between the first point of attachment and the proximal end.

Further features and advantages of the present invention will become apparent to those of ordinary skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

Brief Description of the Drawings

Figure 1 is a schematic illustration of the heart, showing one embodiment of the mitral annuloplasty device of the present invention deployed within the coronary venous system.

Figures 2 and 2A are schematic illustrations of the mitral annuloplasty device shown in Figure 1, in implanted and deployment configurations.

Figure 3 is an overall view and cross-sectional view through a transvenous delivery sheath.

Figure 4 is a schematic illustration of the delivery sheath and two different embodiments of the implant for extravascular remodeling, one with a forming element and one without.

Figure 5 is a schematic illustration of an alternative embodiment of the present invention positioned in an open-loop configuration through the delivery sheath.

Figure 6 is a schematic illustration of a heart, having an alternate embodiment of the mitral annuloplasty and cardiac reinforcement device of the present invention positioned within the coronary sinus and contiguous venous system.

Figures 16A-B show side elevational views of a distal end portion of a delivery assembly detachably coupled to another elongate body that is also adapted for use according to the device assembly shown in Figure 1, and show the elongate body during two modes of operation, respectively.

Figure 16C shows a rear partially cross-sectioned view taken along lines 16C-16C shown in Figure 16B, and shows in shadow two alternative configurations for the elongate body during the mode of use shown in Figure 16B.

Figure 16D shows a side elevational view of the elongate body in the mode shown in Figure 16A.

Figure 16E shows a bottom plan view of the device shown in Figure 16D.

Figure 17A shows a side elevational view of a distal end portion of a delivery assembly coupled to another elongate body which is adapted for use according to the device assembly shown in Figure 14 during one mode of use.

Figures 17B-C show side views of the elongate body shown in Figure 17A, and shows the elongate body during two modes of use, respectively.

Figures 17D and 17E show side elevational views of an alternate construction for the implant of the present invention, in a first configuration and a second configuration, respectively.

Figures 18A-B show side elevational views of two implants, showing alternative slot patterns.

Figure 19 is a bottom plan view of an alternative medical device including a delivery assembly, comprising a handle assembly and a shaft, and an implant configured for remodeling a mitral valve.

Figure 20 is a cross section of the shaft of the medical device of Figure 19 taken along the view line 20-20 of Figure 19.

Figure 21 is an enlarged view of a portion of the medical device of Figure 19, including the implant and a connection assembly for removably connecting the implant to the delivery assembly.

Figure 22 is an enlarged view of the connection assembly of the medical device of Figure 21.

Figure 23 is a plan view of a driver of the delivery assembly of the medical device of Figure 19, viewed apart from the medical device.

Figure 24 is an end elevational view of a hex-shaped distal end of the driver of Figure 23, taken along the view line 24-24 of Figure 23.

Figure 25 is a cross section view of the handle assembly of the medical device of Figure 19.

Figure 26 is a cross section of a portion of the handle assembly of Figure 25 including a driver holder, taken along the view line 26-26 of Figure 25.

Figure 27 is a plan view of the handle assembly of Figure 25 taken along the view line 27-27 of Figure 25.

Figure 28 is a plan view of a slot pattern of the implant of Figure 19.

Figure 29 is an enlarged view of a single slot of the slot arrangement of Figure 28.

very flaccid and flexible, thereby minimizing the risk of erosion of the device 40 through the wall of the great cardiac vein or other aspect of the coronary venous system. The proximal end 42 of the device 40 lies outside the ostium 24 of the coronary sinus 22 and is desirably curved upward so as to anchor against the posterior aspect of the interatrial septum 46. Advantageously, the proximal end 42 of the illustrated device 40 is semicircular in shape and elliptical in profile so that no edges will promote erosion of adjacent tissue.

As an alternative anchor 52 to the distal extension of the device 40, any of a variety of structures may be provided. In general, the deployed device 40 will contact the wall of the coronary sinus 22 along the inside radius of its arcuate path. Thus, a tissue contacting surface 54 on the concave side of the deployed device 40 may be provided with any of a variety of friction enhancing surface structures, such as a plurality of transverse ridges, teeth or other projections, or modified surface textures to enhance friction. Alternatively, tissue engaging or piercing structures such as barbs may be provided on the surface 54 to engage the wall of the coronary sinus 22 to resist movement of the device 40.

While use of such structures as anchors may provide some benefit in certain applications, embodiments herein shown and described are believed to be particularly useful in one aspect specifically because they operate without the need for such aggressive tissue engagement. It will be apparent to one of ordinary skill based upon this disclosure that the presently preferred embodiments provide independent device manipulation and shape control that allow for sufficient forces to be applied to the mitral valve without requiring the possibly harmful effects of puncturing and grabbing tissue within the sinus for the remodeling process. In one regard, the independent action of a barbless design allows for adjustment in both the tightening and loosening directions with reduced risk of significant tissue damage or erosion. In another regard, preferred devices 40 according to at least certain embodiments beneficially maintains its length throughout its modified range of shapes while the sinus and adjacent valve annulus reduce their dimensions under the force of remodeling. In still a further regard, the independent action and lack of tissue piercing and grabbing anchors allow for the device to be removed from the patient after initial implantation within the sinus, such as for example in the event of complications or in applications intended to be temporary remedial measures, such as for bridging a patient. Further to this regard, various shapes and sizes of devices may be required in a given patient before the appropriate one is found according to the observed *in vivo* response to implantation.

The specific dimensions, construction details and materials for the mitral annuloplasty and cardiac reinforcement device 40 can be varied widely, as will be appreciated by those of skill in the art in view of the disclosure herein. For example, dimensional adjustments may be made to accommodate different anatomical sizes and configurations. Materials and construction details can be varied to accommodate different tensioning mechanisms and other considerations.

In general, the device 40 defines an overall length from proximal end 42 to distal end 44. Preferably, the length is within the range of from about 2 cm to about 10 cm in an embodiment such as that illustrated in Figure 2 in which the anchor 52 comprises a distal extension of the body 66 for lodging within the great cardiac vein 28.

The device 40 further comprises a support 58, which may be the body 66 of the device 40 or a separate element positioned therein. In an embodiment in which the support 58 is a separate element contained within the device 40, support 58 may comprise any of a variety of generally axially non-compressible elements such as a metal or polymeric wire or column, ribbon, or "bottomed out" (i.e., fully compressed) spring which facilitates lateral bending but inhibits axial compression upon proximal retraction of forming element 56. A metal ribbon comprising stainless steel, nitinol, or other known materials may be desired in certain embodiments, due to its ability to influence the plane of curvature of the device 40 when in the formed orientation.

In the presently illustrated embodiment, the proximal extension 64 of the forming element 56 extends proximally throughout the length of a deployment catheter, to a control or free end which remains outside of the patient during the deployment procedure. Following placement of the device 40 in the coronary sinus, proximal traction on the proximal extension 64 will reconfigure the device 40 into the formed orientation within the coronary sinus, as will be discussed in connection with the method of use of preferred embodiments. After a sufficient tension has been placed on the coronary sinus 22, the forming element 56 is preferably locked in a fixed axial position with respect to the device 40, to resist distal movement of the forming element 56 through aperture 62. Any of a variety of suitable lock arrangements may be provided. Preferably, the lock 70 is provided on or near the proximal end 42, and, in particular, at or about the aperture 62. The lock may comprise any of a variety of structures, such as a suture knot, locking clamp or ring, an interference fit, ratchet and pall structures, an adhesive bond, or a compression fit, as will be apparent to those of skill in the art in view of the disclosure herein.

The lock 70 (on any of the embodiments herein) may be initially disengaged, so that the forming element 56 may be retracted or advanced freely through the aperture 62 while the physician adjusts the tension on the device 40. After the desired tension is achieved, the lock 70 is activated to engage the forming element in a manner which will depend upon the lock design. Alternatively, the lock 70 may be biased into an engaged configuration, such as with ratchet or cam structures, so that the forming element can only be retracted proximally. Preferably, however, the lock will allow the forming element to be released so that the physician can release tension on the device 40 in the event of momentary over tightening.

Referring to Figures 7-9, there is illustrated one preferred embodiment of a releasable lock 70. Although the lock 70 is illustrated as a discrete component of the system, it can alternatively be formed integrally with or attached to the proximal end of the body 66. The lock 70 comprises a body 114, which may be in the form of an annular collar with a central aperture for axial movement over the forming element 56. The body 114 is provided with one or two or three or more releasable locking elements 126, which incline radially inwardly in the proximal direction.

Each locking element 126 is provided with at least one engagement surface 122 for engaging the forming element 56. The forming element 56 may be provided with any of a variety of friction enhancing surface textures or structures to enhance the locking function. Thus, a locking zone along the forming element may be provided with

if present, support 58 may be positioned within a suitable length of tubing formed such as by extrusion. The tubing may be drawn down to a reduced diameter at the distal end 44. Additional post extrusion steps may be used to produce the desired cross-sectional configuration. Manufacturing techniques for the present invention will be apparent to those of skill in the art in view of the disclosure herein.

Any of a variety of additional features may be added to the device 40, depending upon the desired clinical performance. For example, the outside surface of the body 66 may be provided with any of a variety of coatings, such as poly-paraxylene, sold under the trademark PARALENE, PTFE or others to improve lubricity; heparin or other antithrombogenic agents; elastomers such as silicone, neoprene, latex or others to soften the surface and reduce the risk of trauma to the vascular intima, and the like. Adhesion enhancing surfaces may be provided, such as ePTFE patches or jackets, to promote cellular ingrowth for long term anchoring. In addition, depending upon the deployment system design, the body 66 may be provided with a guidewire lumen extending axially therethrough, to allow the body 66 to be advanced distally over a guidewire during placement at the treatment site.

The device 40 may be implanted within the coronary sinus 22 either through direct surgical (e.g. thoracotomy, with or without sternotomy) access, such as in combination with another surgical procedure, via port access, or remotely by way of a percutaneous or surgical cut down access to the venous system. Preferably, the device 40 is implanted in a transluminal procedure, such as by way of a percutaneous access at one of the internal jugular, subclavian, or femoral veins.

Referring to Figure 3, there is disclosed a deployment, or delivery system 72 for deploying the device 40 of the present invention. The deployment system 72 desirably comprises an introducer sheath or catheter 74 for percutaneous venous access procedures. In some circumstances, however, the system 72 includes a first introducer sheath 74 for simply gaining percutaneous access into the vasculature at a remote location from the heart, and a slideably engageable second introducer sheath or guiding catheter is deliverable through such a percutaneous introducer sheath. Introducer sheath 74 has an elongate flexible tubular body 76 extending from a proximal end 78 to a distal end 80. A preset curve 82 is provided near the distal end 80 of the tubular body 76, as is known in the cardiac access catheter arts. At least one lumen 84 extends through the tubular body 76. In one embodiment, the lumen 84 has a noncircular cross section, such as an ellipse having the major axis perpendicular to the plane of curvature of the introducer sheath 74.

Introducer sheaths are well known in the art, and may be manufactured by extrusion, for example, with or without a braided reinforcement structure in the wall. The length and diameter of the introducer sheath 74 may vary considerably, depending upon the dimensions of the device 40 as well as the access point for percutaneous access into the vascular system. For a femoral vein access, for example, the introducer sheath may have a length within the range of from about 80 cm to about 120 cm. Preferably, the outside diameter of the introducer sheath 74 is no more than about 10 French (approximately 3.3 mm).

With reference to Figure 4, a pusher or dilator 86 as shown provides specific embodiments for a broader aspect that is a delivery member used in an overall assembly for delivering, i.e. advancing or pushing, the device

coil, or other structure known in the medical guidewire arts. Preferably, the first and second control lines have a diameter within the range of from about 0.009 inches to about 0.018 inches, although larger diameters may also be used, particularly for the first control line 108.

The distal control line 110 is advanced through an introducer sheath into the great cardiac vein 28 and then through anastomotic connections 29 into the middle cardiac vein 30. Continued advancement results in the tip of the distal control line 110 emerging from the ostium 24 of the coronary sinus 22. The control line 110 is then harnessed with a snare and pulled retrogradially through the delivery catheter as illustrated in Figure 5. The body 102 is then pulled into the coronary venous system. The body is preferably larger in diameter than the first and second control lines 108 and 100, and preferably elliptical or otherwise noncircular in cross section. This shape enlarges the transverse tissue contact surface area and reduces the risk of erosion when tension is applied to the loop. Both the proximal and distal ends of the loop are threaded through a locking clip 112. A dilator is used to push the clip 112 through the delivery catheter to the level of the coronary sinus ostium 24. Using counter traction on the dilator and the first and second control lines 108 and 110, the clip 112 is cinched on the loop until the requisite degree of tension is produced. Finally, the device is separated from the delivery system using a cutting tool to cut the first and second control lines 108 and 110, and possibly proximal and distal ends 104 and 106 to the extent they extend proximally from clip 112.

The overall length of the embodiment illustrated in Figure 5 is desirably sufficient so that both of the first control line 108 and second control line 110 can extend outside of the patient, while the body 102 extends throughout the pathway of the ventricular girdle 100, substantially as illustrated in Figure 6. For a percutaneous femoral vein access, the overall length of the device is preferably at least about 200 cm, and generally within the range of from about 220 cm to about 260 cm. The length of the body 102 from proximal end 104 to distal end 106 is preferably sufficient to form a closed loop as illustrated in Figure 6. Although both heart size and the shape of the vascular pathway will vary from individual to individual, the length of the body 102 is generally within the range of from about 6 cm to about 12 cm. The body 102 may be injection molded, extruded as a tube, or coextruded over the wire that forms first and second control lines 108 and 110. Preferably, the body 102 either comprises, or is coated with, a material sufficiently compliant to minimize trauma to the vascular intima. In addition, the transverse width of a tissue contacting surface 114 on body 102 is preferably sufficient to distribute compressive force to minimize the risks of localized pressure necrosis within the coronary veins.

Figures 10-13B illustrate another particular device assembly 200 that includes various aspects readily adapted for use according to various of the embodiments discussed above. In general, Figure 10 is an overall view of assembly 200 that includes a delivery assembly 210 engaged to a prosthesis, or implant 250. According to similar overall delivery systems and methods elsewhere herein described, prosthesis 250 is adapted to be delivered in a first condition and shape into a vessel at least in part by manipulation of delivery assembly 210. Once in the desired region of the target vessel, prosthesis 250 is adapted to be adjusted to a second condition and shape within the vessel in order to influence an adjacent tissue structure. As also elsewhere herein described, a particularly

keyed interface may be employed as shown in Figures 12A-B. According to this mode, a shaped proximal fitting 253 on the proximal end 252 of prosthesis 250 is adapted to mate as a male counterpart into a shaped aperture or fitting on the distal end 212 of outer member 215. This keyed interface allows for rotational coupling between the members in a similar manner as just described for the inner member 225 and rotational coupler 280, and may allow for a more releasable coupling with reduced friction upon axial detachment of the members.

According to another aspect, the rotational forces from rotational coupler may be converted to deflection forces on the prosthesis 250 according to one example as illustrated in the specific illustrative embodiment of Figures 10-13B, and in particular detail in Figures 13A-B. Prosthesis 250 includes a generally tubular wall or body 260 that has an inner lumen 262 and extends from the proximal end portion 252 to the distal end portion 254 of prosthesis 250. Secured along proximal end portion 252 is a nut fitting 263 that has a grooved inner bore 264 which communicates with inner lumen 262. Further to this specific embodiment, rotational coupler 280 is a screw member with outer helical threads 285 engaged within the mating threads of an inner surface (not shown) of a bore lumen such that a distal end of screw member 285 extends distally within lumen 262 and terminates at a second key fitting 287 similar to the shaped proximal end portion 282 and also having an aperture 288. Similar to the proximal end of rotational coupler 280, another flexible member or filament 290 is looped through aperture 288 such that two arms 292,294 extend distally therefrom to an attachment point along distal end portion 254 of prosthesis 250. Because nut fitting 263 is fixed in relation to outer tubular body 260, and because that tubular body is held relatively fixed position as provided above, rotation of rotational coupler 280 moves coupler 280 proximally relative to body 260. This proximal axial translation of rotational coupler 280 puts tension on filament 290, which puts tension on the body 260 due to the distal attachment. This tension on outer body 260 forces a deflection of the body 260. Therefore, rotational force is converted into a tensile force which, in turn, causes radial deflection of the body 260 relative to the longitudinal axis L of the device 250. In other words, the body 260 is deflected about an axis that is transverse to the longitudinal axis L.

The forced deflection described immediately above may be controlled in a particular plane by providing a composite structure within prosthesis 250 that is engineered to respond, i.e. yield, to these forces in a prescribed way. In the specific desirable embodiment shown, a relatively rigid spine member 270 is provided within lumen 262 of outer tubular body 260. This spine member 270 is more rigid and more resistant to axial forces, especially tensile forces, than the material of outer tubular body 260 alone. Therefore, providing spine member 270 along only one radial position along the circumference of the prosthesis 250 creates a bias on the device 250 to deflect away from the spine 270 toward a more compressive region of the device 250. Such composite design may further include a laminate structure, a composite structure - such as an imbedded wire reinforced wall structure, or may be achieved by engineering material variations in the device, such as for example by thinning, thickening, hardening, or softening the material at one location along the outer tubular body 260 relative to another region to urge the body 260 to deflect at a desired location.

Thus, the method of implantation preferably further comprises the steps of monitoring the degree of mitral regurgitation during, and preferably also before and following the implantation and/or reconfiguration steps. The degree of mitral regurgitation may be monitored such as by transesophageal echo cardiography, intracardiac echo cardiography, fluoroscopy using radiocontrast in the left ventricle (LVgram), or left atrial or pulmonary capillary wedge pressure tracings, as are understood in the art, during the incremental restriction of the mitral annulus and/or left ventricle step. Once a sufficient reduction in regurgitation has been achieved for a particular patient in the physician's judgement, the device 250 may be locked and the delivery assembly 210 detached from the device 250 and removed from the patient.

The method may additionally comprise the step of measuring the coronary sinus 22 and/or other coronary vein, and selecting an appropriately sized implant 250 from an array of implants of varying sizes. Such parameters may include diameter, length, or radius of curvature of the arc of the sinus. The appropriately sized implant 250 is thereafter positioned within the target vein. The implant 250 is thus preferably provided in a graduated array of sizes, so that the optimal size can be selected for each patient. The size of the coronary sinus 22 or other vein can be measured using any of a variety of techniques, such as echo cardiogram, MRI, CT Scan, or angiography as is understood in the art. Moreover, as is apparent to one of ordinary skill, measuring a parameter of the coronary sinus 22 generally provides indicia of certain parameters of the mitral valve and its annulus, such as for example mitral valve diameter, in which case either the coronary sinus parameter or the mitral valve parameter may provide the requisite information for choosing an appropriately dimensioned device 250 from the kit.

It follows that such mitral valve parameters may further be measured directly, such as by various of the methods just described, in order to generate the values used for choosing the appropriate device 250. Once a parameter for an anatomical feature is measured as herein described, its value is generally estimated according to the accuracy of the respective measuring tool – it is contemplated that persons without specialized medical skills or training can choose the appropriate medical device 250 from the kit once armed with this estimated value. For example, packaging for each device 250 of the kit may indicate the respective dimensions that are unique to that device 250 with respect to other devices of the kit, and the estimated value of the measured anatomical parameter may simply be compared.

It is contemplated and apparent that various of the embodiments herein described are adapted to accomplish manipulation of the coronary sinus 22 for mitral annulus reduction without substantially altering the length of the device 250 within the sinus 22. This may provide a benefit by increasing the useful purchase of the device 250 along the coronary sinus 22 and circumferentially around the mitral annulus as the sinus length and/or annulus diameter may be reduced during remodeling from the radial deflection of the prosthetic device 250. This may also mean that the dimension of the device 250 in a kit of devices may not directly correspond to the estimated value of the anatomical parameter that is measured. For example, the compared value of the measured device parameter may be shorter than an estimated coronary sinus 22 length due to a possible shortening of the sinus 22 during device 250 treatment. Or, the anatomical parameter may be estimated from an initial value based upon an

sinus. An additional introducer sheath 303 may also be provided in order to allow for percutaneous access into the vasculature at the introduction site.

As shown in one embodiment in Figure 15B, once in the coronary sinus the elongate body 320 is adapted to be adjusted from the first implantation (flexible) configuration to a second (relatively rigid) remodeling configuration that has a shape that is adapted to remodel the mitral valve annulus. According to the embodiment shown in Figure 15B, this shape is generally adapted to provide an external force onto the annulus in order to reduce its diameter along at least one transverse axis, such as according to the arcuate shape shown that at least in part grips down onto a portion of the circumference of the valve to provide a diameter reducing force. As is also shown in phantom, the arcuate shape may take different forms in terms of degree, and in a further highly beneficial application is controllable and selectable between various or through a continuous range of degrees. Such controllability according to the embodiment shown is also selective between intermediate deflectable portions 360, 370, 380, as is shown in Figure 15B and will be further developed below.

Figure 15C illustrates a feature related to the deflection mode of operation for the embodiment shown in Figures 15A-B and with further reference to the increased detail shown in Figures 15D-H. More specifically, elongate body 320 is constructed in a manner that is shown to substantially isolate deflection in the second configuration along one reference plane while substantially preventing deflection or bending out of that plane. This is accomplished according to the embodiment shown as follows.

Elongate body 320 is constructed from tubular wall 325 that extends continuously along the length of the deflectable portions 360,370,380 of the elongate body 320. An array or plurality of distinct, discontinuous slots or voids 330 are formed within the wall 325, each void 330 having an elongated shape that is transverse to the longitudinal axis. These voids 330 are shaped as follows. Each void 330 has an elongate shape that is transverse to the longitudinal axis.

By further reference to the specific embodiment of Figures 15A-G, transverse voids 330 have a central groove-shaped region with two adjoining portions 332, 334 that converge at an apex 333 along the longitudinal axis. Such a shaped void 330 is defined at least in part by two opposing shaped surfaces of two adjacent, longitudinally opposing portions 340, 350 of the wall of the elongate body 320. One of these portions 340 desirably assumes a convex shape and the other portion 350 is desirably concave around the apex 333. These shaped surfaces 340, 350 are preferably in a nested configuration with the convex portion 320 positioned within the concave portion 350. In this arrangement, lateral movement of one of the adjacent wall portions 340, 350 relative to the other portion 340, 350 is substantially prevented by a mechanical interference with the other adjacent portion 340, 350. This is illustrated by way of interrupted arrows signifying prevented lateral movement in Figure 15C. As shown in that Figure, the relative nesting of adjacent portions 340, 350 of the elongate body 320 provides a mechanical interference to radial deflection along a first plane and substantially isolates deflection of the elongate body 320 along a second plane upon application of axial bending forces.

According to one specific embodiment that has been observed to be useful, the apertures for this attachment embodiment are generally between about 0.020 inches and about 0.022 inches in diameter with similar longitudinal spacing, and the distal end for the seated forming elements are between about 0.012 and about 0.014 inches in diameter. Further to that embodiment, wall 325 is generally constructed from a tubular, stainless steel wall or hypotube with a plurality of grooved voids 330 formed therein according to a pattern similar to that shown and described by reference to Figures 15D-F. The respective forming elements are soldered to the respective attachment points using gold/tin solder. Further to this useful embodiment, grooves such as shown and described by reference to Figure 15A-G were formed in the underlying stainless tube by laser cutting, though other well known techniques such as hand grinding, mechanical cutting, photo-lithography, etc. may alternatively be used.

As previously described herein, the applied force from the forming elements 365, 375, 385 are generally an axial force between the attachment points 361, 371, 381 to the elongate body 320 and a proximal location (not shown) along the elongate body 320 that is proximal to that deflectable portion. According to the specific embodiments shown this force is generally between the attachment points 361, 371, 381 and the proximal end portion of the elongate body 320. The elongate body 320 may generally be held during forced deflection by means of a holding device (not shown) in order to substantially fix the proximal end portion of the elongate body 320 relative to the deflectable portion so that the axial force may be applied between those portions in situ. While the proximal manipulation of the forming elements 320 in order to apply the deflection force to the deflectable portions 360, 370, 380 may be axial as just described, it may in another regard be rotational.

Each deflectable portion 360, 370, 380 is substantially axially rigid and non-compressible relative to the longitudinal axis L, and therefore the overall axial length of elongate body 320 remains substantially constant between the first and second configurations. However, each deflectable portion is relatively flexible along a radial axis transverse to the longitudinal axis such that the deflectable portion is adapted to bend radially upon application of an axial force between a distal location on the elongate body at or distal to a distal end of the deflectable portion and a proximal location along the elongate body 320 proximal to that deflectable portion. In one regard, the elongate body 320 may be generally axially non-compressible or non-expandable between each deflectable portion 360, 370, 380 and the proximal end portion of the elongate body 320, such that each deflectable portion 360, 370, 380 is adapted to bend radially upon application of a compressive or tensile axial force, respectively, on the elongate body 320 between the distal location and a proximal location that is at the proximal end portion of the elongate body 320.

In still a further regard, other constructions for elongate body 320 may also provide for the combination of an integral and continuous wall 325 from the proximal end portion to the distal end portion of the body and a controlled radial bending response to axially compressive or tensile forces. In addition or in the alternative to the continuous integral wall incorporating the formed voids 330, the wall 325 may also include an engineered composite support structure with engineered support elements that are arranged to control the spacial strain response to the stress of the applied forces. Other suitable shapes for voids 330 may also be acceptable.

elongate body 320. However, the specific structure for elongate body 320 as just described for Figure 17A may also have multiple deflectable regions with multiple interfacing forming elements, as previously described above for the other embodiments. However, Figures 17B-C and Figures 17D-E in the single forming element form provide a simplified illustration for a detachable, permanent implant embodiment of the device of Figure 17A and of a non-detachable, temporary implant embodiment, respectively.

More specifically, Figures 17B-C show forming element 365 that includes a proximal tension member 366 and a distal tension member 367 with interlocking hooks. Distal tension member 367 includes a ratchet assembly 368 with teeth 369 that interact with a pawl 328 that is secured to the proximal end portion of elongate body 320. Distal tension member 367 is drawn proximally relative to elongate body 320 by means of proximal pulling on proximal tension member 366 via their interlocking hook coupling. Elongate body 320 is held substantially stationary by advancing inner member 312 distally to house the interlocked hooks 366, 367 and distally abut the proximal end portion of elongate body 320. Accordingly, ratchet 368 is drawn proximally across pawl 328 which responds by deflect over the teeth 369 and locking back down between the teeth 369. Additional proximal movement of member 367 continues to tension elongate body 320 that responds by deflecting as shown in Figure 17C and as otherwise herein described. However, by releasing the interlocking hooks distally from inner and outer delivery members 312, 310, respectively, the configuration for pawl 328 desirably operates as a lock against any distal motion of member 367 in response to the tension. Therefore, the elongate body 320 is left implanted in the coronary sinus locked in the contracted configuration shown.

It is important to appreciate that the prosthetic elongate body embodiments herein shown and described may be used in an overall permanent implant assembly and procedure, or may be incorporated into a temporary implant design. The embodiment of Figures 17D-E show a similar embodiment as that shown in Figures 17B-C, except with the significant distinction that the elongate body 320 is preferably not arranged for permanent implantation. Proximal delivery member 310 is secured to elongate body 320 and remains extending outside of the patient's body while elongate body 320 is deployed within the coronary sinus for temporary reconfiguration and remodeling of the mitral valve. As one benefit of such design, a lock is unnecessary in the distal coupling assembly between delivery member 310 and elongate body 320. Though a lock may nevertheless be incorporated into such a design, such lock should preferentially be disengageable in order to allow for in situ adjustment between the differing shapes of the first and second configurations. In addition, the structural elements of the present design is not required to sever or otherwise detach or uncouple the forming member 365 where it extends from the delivery member 310 to the elongate body 320.

Additional variations are further contemplated for achieving controlled, desired flexion of the elongate body 320 according to the present embodiments, as is further illustrated by the tapering body design in Figures 18A-B. More specifically, Figure 18A shows a tapering body 320 having a wall 325 with a distally reducing outer diameter between a proximal end portion 321 and a distal end portion 322. As shown, this particular embodiment incorporates the tapered design in combination with the V-shaped grooved void array of Figures 15A-H. However,

provides an extravascular tissue remodeling device for positioning within a vessel in order to remodel an extravascular tissue structure adjacent to that vessel.

Still another aspect provides a mitral valve remodeling device with a prosthesis that is adapted to be delivered in a first configuration with a first shape into a coronary sinus and to be adjusted within the coronary sinus to a second configuration with a second shape that is adapted to remodel a mitral valve adjacent to that coronary sinus. According to one mode of this aspect, the prosthesis includes an elongate body that is a generally tubular member. The tubular member has an integral wall that forms a passageway extending along a longitudinal axis between a proximal end portion and a distal end portion. The integral wall also has at least one void formed within the wall that substantially influences the second shape in the second configuration for the elongate body. In one beneficial application of this mode, the integral wall has an array of such voids that are distinct, discontinuous and spaced along the longitudinal axis. In a further beneficial application, each of the array of voids has an elongate shape that is transverse to the longitudinal axis. In one variation, at least one of these transverse voids spans across at least about 180 degrees of the circumference of the elongate body. In a further variation, at least one of the transverse voids spans across more than about 300 degrees of the circumference of the elongate body, and in still a further variation at least one void spans across between about 300 degrees and about 315 degrees of the circumference.

A further variation of the voided, integral wall application allows for a bending response in more than one plane. The shape for each of the voids is such that the elongate body in the second configuration is adapted to experience at least a controlled amount of bending in more than one plane.

In another variation, at least one of the transverse voids has a groove-shaped region with two adjoining portions that converge at an apex along the longitudinal axis. Such a shaped void is defined at least in part by two opposing shaped surfaces of two adjacent portions of the wall of the elongate body: one that is convex and one that is concave around the apex. These shaped surfaces are in a nested configuration with the convex positioned within the concave, such that lateral movement of one of the adjacent wall portions relative to the other is substantially prevented by a mechanical interference with the other adjacent portion. This relative nesting of adjacent portions of the elongate body provides a mechanical interference to radial deflection along a first plane and substantially isolates deflection of the elongate body along a second plane upon application of axial bending forces. In one more detailed variation of these nested, shaped voids, the adjacent wall portions converge distally to the apex of the respective void. In another detailed variation, the adjacent wall portions converge proximally along the elongate body to the apex. Still a further variation includes discrete voids that converge distally to the apex, and also includes other voids converging proximally.

According to another mode of the mitral valve remodeling assembly aspect of the invention, the prosthesis includes an elongate body that extends along a longitudinal axis between a proximal end portion and a distal end portion. The elongate body has more than one region along the longitudinal axis that is at least partially

voids, the wall may also include an engineered composite support structure with engineered support elements that are arranged to control the spacial strain response to the stress of the applied forces.

In yet a further variation, the deflectable portions bend radially as the elongate body is adjusted with force from the first to the second configuration in a manner such that the overall axial length of the elongate body along at least the deflectable portions does not substantially change during such adjustment.

Another aspect of the invention is a prosthesis that is implantable within a vessel of a patient and that includes an elongate body having a substantially tubular member with an integral, continuous wall extending along a longitudinal axis between a proximal end portion and a distal end portion. An array of distinct, discontinuous voids are formed within the tubular member and are spaced along the longitudinal axis. Each void of the array has an elongated shape transverse to the longitudinal axis. In one mode of this aspect, the array of voids are arranged in a manner such that a substantially linear portion of the wall remains as a spine that is uninterrupted by the voids and extends along a spine axis that is substantially aligned with the longitudinal axis between the proximal end portion and the distal end portion.

Figure 19 illustrates an additional construction of a medical device 400 adapted to position an implant 402, or prosthesis, into the coronary sinus or other treatment site. Similar to the embodiments described above, medial device 400 includes a handle assembly 404 at a proximal end, while the implant 402 is located at a distal end. The handle assembly 404 and implant 402 are connected by an elongate, flexible catheter body 406. Desirably, the body 406 is or includes an extrusion of a material having sufficient column strength, that is, it resists compression in an axial direction, while permitting the body 406 to bend in a radial direction. Any of a variety of polymers well known in the transluminal catheter arts, such as HDPE or PEBAX, is used to form the body 406. However, other suitable materials may also be used. In one embodiment, the body 406 has an outside diameter of approximately 0.094 inches.

With reference to Figure 20, a plurality of lumens or passages extend in an axial direction along the length of the catheter body 406. The illustrated extrusion includes three small lumen 408, 410, 412 and one larger lumen 414. The small lumen 408, 410, 412 may be disposed substantially within one half of the circular cross section of the body 406 and each has an inside diameter of approximately 0.024 inches. The larger lumen 414 is desirably positioned substantially within a half of the circular cross section of the body 406 opposite the small lumen 408, 410, 412 and may have a diameter of approximately 0.044 inches. Collectively, the lumen 408, 410 and 412 allow control components 400 (e.g., forming elements 365, 375, 385 of Figures 15 and 16) of the medical device 400 to extend from the handle assembly 404 to the implant 402 while being protected within the shaft 406. As will be described in detailed below, the control components convert operational movements of the handle assembly 404 into desired resultant movement of the implant 402. The larger lumen 414 may be used to rotatably receive a driver 436 as will be discussed. Additionally, one or more of the lumen may be used to permit irrigation to the coronary sinus, or other desired purposes.

of the medical device 400 such a driver 436. In the illustrated embodiment, the cavity 434 is hex shaped and sized to receive a hex-shaped distal end portion 438 of the driver 436 (Figure 24).

A male connector 440 is connected to the head portion 432 of the screw 428. The male connector 440 includes a shaft portion 442 and a head portion 444. The head portion 444 of the male connector 440 has a larger diameter in that of the shaft portion 442. A passage 446 desirably extends axially through the male connector 440 and defines a first portion 448 and a second portion 450. The first portion 448 of the passage 446 is located proximate the head portion 444 of the male connector 440 and has a larger diameter than that of the second portion 450, which is located proximate the shaft portion 442 of the male connector 440. A transition between the first portion 448 and the second portion 450 defines a shoulder surface 452 which extends generally transverse to the longitudinal access of the male connector 440. The first portion 448 of the passage 446 is preferably sized and shaped to receive the head portion 432 of the screw 428. Desirably, the head portion 432 of the screw 428 abuts the shoulder 452 of the passage 446.

An annular collar 454 secures the head portion 432 of the screw 428 within the passage 446. Desirably, the outer diameter of the collar 454 is approximately the same as the outer diameter of the head portion 444 of the male connector 440. The collar 454 includes an inner flange portion 456 which is sized and shaped to fit within the first portion 448 of the passage 446 of the male connector 440 in a press fit configuration.

In a similar manner to the embodiments described above, the implant 402 desirably includes a wire 458 which is operational for moving the implant 402 from a first, delivery configuration to a second, remodeling configuration. The wire 458 is desirably anchored to a distal end of the implant 402 by soldering or any of the methods described above, or any other suitable method as may be determined by one of skill in the art. Preferably, a proximal end of the wire 458 is anchored to one of the male connector 440 and the collar 454. Alternatively, the proximal of the wire 458 may be attached to another portion of the screw 428, as described in relation to the embodiments above. Desirably, the proximal end of the wire 458 is anchored to the male connector 440 and, preferably, is thermally welded or otherwise bonded to the male connector 440. However, other suitable methods of attachment may also be used, such as an adhesive or mechanical fastener, for instance. Preferably, the male connector 440, the collar 454 and the nut 422 include corresponding slots 460, 462, 464, respectively, which are sized and shaped to permit clearance for the wire to pass therethrough.

As described above, the delivery assembly 401 is preferably capable of being releasably coupled to the implant 402. For this purpose, a female connector 466 is desirably coupled to the distal end of the shaft 406. The female connector 466 is preferably hollow and substantially cylindrical in shape. The distal end of the female connector 466 includes a plurality of prongs, or finger portions 468, which are able to flex radially outward to permit the female connector 466 to engage the shaft portion 442 of the male connector 440. Desirably, the resiliency of the material from which the female connector 466 is constructed enables the female connector 466 to firmly grip the male connector 440. Desirably, an inner surface of the finger portions 468 defines an annular projection 470 which corresponds with an annular groove 472 of the male connector 440. When the female

400 and the proximal handle 500 is configured to be rotatable with respect to the distal handle 502, thus rotating the driver 436 to selectively move the implant 402 between a delivery position and a remodeling position.

The distal handle 502 is generally cylindrical in shape and defines an internal cavity 504. A threaded aperture 506 extends from the cavity 504 through the distal end of the distal handle 502 and is substantially concentric with a longitudinal axis of the handle assembly 404. A proximal connector 508 is desirably retained by a threaded connection with the threaded aperture 506 and extends axially from a distal end of the distal handle 502. Desirably, the distal handle 502 additionally includes a threaded aperture 510 situated substantially transverse to the longitudinal axis and intersecting the threaded aperture 506. A set screw 512 is advantageously in threaded connection with the threaded aperture 506 and may be tightened against the proximal connector 508 to inhibit undesired axial movement of the proximal connector 508 with respect to the distal handle 502.

The proximal connector 508 includes a central aperture 514 passing axially therethrough. The central aperture 514 is desirably substantially concentric with the longitudinal axis of the handle assembly 404 and receives the shaft 406 in a fixed axial position with respect to the distal handle 502. The shaft 406 may be fixed to the proximal connector 508 in any suitable manner, such as by adhesives or thermal welding, for example.

In the illustrated embodiment, the cavity 504 opens through the proximal end of the distal handle 502 to receive a handle connector 516, preferably through a threaded connection therebetween. In addition, a set screw arrangement 517, similar to that describe above in relation to the proximal connector 514, is desirably provided to inhibit undesired movement of the handle connector 516. The handle connector 516 is configured to connect the proximal handle 500 and the distal handle 502, while allowing relative rotation therebetween. The handle connector 516 desirably includes a shaft portion 518 extending proximally away from the distal handle 502. A cylindrical passage 520 extends axially through the proximal handle 500 and is sized to be rotatably mounted on the shaft portion 518 of the handle connector 516.

Preferably, the proximal handle 500 includes a handle release assembly 522 that permits releasable engagement to the distal handle 502. The release assembly desirably comprises an annular release collar 524 surrounding the proximal handle 500. The release collar 524 is sized to allow axial movement with respect to the proximal handle 500. A plurality of wire retainers 526 (two shown) releasably engage the shaft portion 518 of the handle connector 516 to selectively secure the proximal handle 500 in a fixed axial position with respect to the distal handle 502. Each of the wire retainers 526 include a short leg 527, which is circular in cross-section and terminates in a ball end 528, and a long leg 529, which is preferably rectangular in cross-section. Desirably, the short leg 527 and the long leg 529 define an angle of approximately 75° between them when the wire retainer 526 is in a relaxed position. Preferably, each wire retainer 524 is constructed from a variety of stainless steel and a total of four wire retainers 526 are employed.

In the illustrated embodiment, the long leg 529 of the retainer 524 is held between an outer surface of the proximal handle 500 and an inner surface of the release collar 524 and, preferably, within a groove 530 defined by the proximal handle 500. A plurality of apertures 532 extend radially through the proximal handle 500 near its distal

The handle pin 546 is desirably substantially cylindrical in shape and defines an internal cavity 556 extending from an open proximal end to a closed distal end of the handle pin 546. The closed distal end of the handle pin 546 includes a pair of apertures 558, 560 extending axially therethrough, opening into the cavity 556. The aperture 558 is sized and positioned to permit the driver 436 to pass there through. The aperture 560 is sized to receive a proximal end of a detach wire 562. The detach wire 562 extends from the handle pin 546 to the cover 474 (Figure 22) through one of the apertures 408, 410, 412 of the shaft 406. The detach wire 562 is secured to the cover 474 by any suitable method, such as thermal welding, adhesives, or mechanical fasteners, for example. A set screw arrangement 564, similar to those described above, is utilized to secure the detach wire 562 within the aperture 560 for axial movement with the handle pin 546. Thus, when the detach collar 544 is moved toward the proximal end of the handle assembly 404, the detach wire 562 pulls the cover 474 to uncover the finger portions 468 of the female connector 466. When the cover 474 is in this position, the female connector 466 is able to be disconnected from the male connector 440 and, thus, the delivery assembly 401 is able to be disconnected from the implant 402, as described above.

The handle assembly 404 also desirably includes a detach collar lock arrangement 566 to substantially prevent undesired movement of the detach collar 544. The lock arrangement 566 preferably includes a threaded aperture 568 passing radially through the distal handle 502. A lock screw 570 is provided for threaded engagement with the threaded aperture 568. The lock screw 570 includes a head portion 572, which interferes with movement of the detach collar 544 toward a proximal end of the handle assembly 404 when the lock screw 570 is screwed substantially fully into the aperture 568. The lock screw 570 may be backed partially, or fully, out of the aperture 568 to permit desired movement of the detach collar 544 toward the proximal end of the handle assembly 404.

Operation of the medical device 400 is substantially similar to the embodiments described above. Preferably, before the procedure is initiated, the lock screw 570 is positioned to prevent undesired movement of the detach collar 544, which could result in premature detachment of the delivery assembly 401 from the implant 402. Once the implant 402 has been desirably positioned within the coronary sinus by a suitable method, such as described above, the proximal handle 500 is rotated with respect to the distal handle 502 to cause rotation of the driver 436. Rotation of the driver 436 results in corresponding rotation of the screw 426 which, in turn, causes the implant 402 to move from a delivery configuration to a remodeling configuration, as described in detail above. The direction of rotation of the proximal handle 500 will vary depending on the orientation of the threaded connection between the screw 428 and the nut 422. However, if a right hand thread orientation is used, the proximal handle 500 will be rotated counter-clockwise to move the implant 402 from a delivery configuration to a remodeling configuration.

When the implant 402 has achieved a desired remodeling configuration, the lock screw 570 is backed off from its locked position to permit movement of the detach collar 544. The detach collar 544 may then be moved toward the proximal end of the handle assembly 404, thereby retracting the cover 474 and exposing the finger portions 468 of the female connector 466. The handle assembly 404 may then be pulled with a sufficient force to

shaped" recess 610 of surface 606. Alternative complementary configurations such as a chevron may also be used. An axis Av of both the projection 608 and the recess 610 is substantially parallel to the longitudinal axis of the implant 402.

An axial distance between the substantially transverse portions of the surfaces 604, 606 defines a width Wv of the void 602. The Wv of the void 602 may be varied, depending upon the desired performance. In general, widths within the range of from about 0.010 to bout 0.040 inches are often used. In the illustrated embodiment, the width Wv is approximately 0.015 inches. Desirably, a distance between at least a portion of both sides of the projection 608 and recess 610 is less than the void width Wv and defines a pair of interference portions 612 between the surface 604 and the surface 606.

The interference portions 612 inhibit the implant 402 from moving out of a plane defined by the longitudinal axis of the implant 402 as it moves from a delivery configuration to a remodeling configuration. Advantageously, the surfaces 604, 606 contact one another in the interference portions 612 of the void 602 in response to a force urging the implant 402 to curve out of plane. Thus, with the illustrated arrangement, the implant 402 is maintained within the desired plane while moving from a delivery configuration to a remodeling configuration. Alternatively, the void 602 may be configured to permit out of plane movement of the implant 402 if such is desirable, as will be appreciated by one of skill in the art. For example, only one interference portion 612 may be provided or the distance between the surfaces 604, 606 may be increased in the interference portion 612.

Although the present invention has been described in terms of certain preferred embodiments, it may be incorporated into other embodiments or performed through other steps by persons of skill in the art in view of the disclosure herein. In addition, features from any one of the embodiments disclosed herein may be incorporated into other embodiments as will be apparent to those of skill in the art. The scope of the invention is therefore not intended to be limited by the specific embodiments disclosed herein, but is intended to be defined by the full scope of the following claims.

17. A medical apparatus as in Claim 14, wherein the anchor comprises at least one barb for piercing the wall of the vessel.

18. A medical apparatus as in Claim 1, wherein the apparatus has an axial length of no more than about 10 cm.

19. A medical apparatus as in Claim 18, wherein the maximum cross sectional dimension through the apparatus is no more than about 10 mm.

20. An implant for positioning within a patient, comprising:

an elongate flexible body having a proximal end and a distal end, and a longitudinal axis extending therebetween, and first and second opposing sides extending along the implant body at least part way between the proximal end and the distal end, the first side having a fixed axial length, and the second side having an adjustable axial length;

at least a first forming element extending through the body to a distal point of attachment to the body; and

a detachable coupling on a proximal portion of the body, for removably attaching the body to a deployment catheter;

wherein manipulation of the first forming element deflects at least a first portion of the body away from the longitudinal axis.

21. An implant as in Claim 20, wherein the body comprises a tubular wall.

22. An implant as in Claim 21, wherein the tubular wall is substantially noncompressible along the first side.

23. An implant as in Claim 22, comprising a plurality of voids in the wall along the second side, thereby permitting axial shortening of the second side.

24. An implant as in Claim 23 wherein at least some of the voids comprise slots through the wall, extending generally transverse to the longitudinal axis.

25. An implant as in Claim 24 comprising at least 10 transverse slots in the wall of the second side.

26. An implant as in Claim 24 comprising at least 20 transverse slots in the wall of the second side.

27. An implant as in Claim 20, wherein the first forming element comprises an axially movable element.

28. An implant as in Claim 20, wherein the first forming element comprises a pull wire.

29. An implant as in Claim 20, further comprising at least a second forming element.

30. An implant as in Claim 29, wherein manipulation of the first forming element introduces a first curve in the body, and manipulation of the second forming element introduces a second curve in the body.

31. An implant as in Claim 20, wherein distal movement of the forming element causes axial elongation of the second side thereby bending the implant.

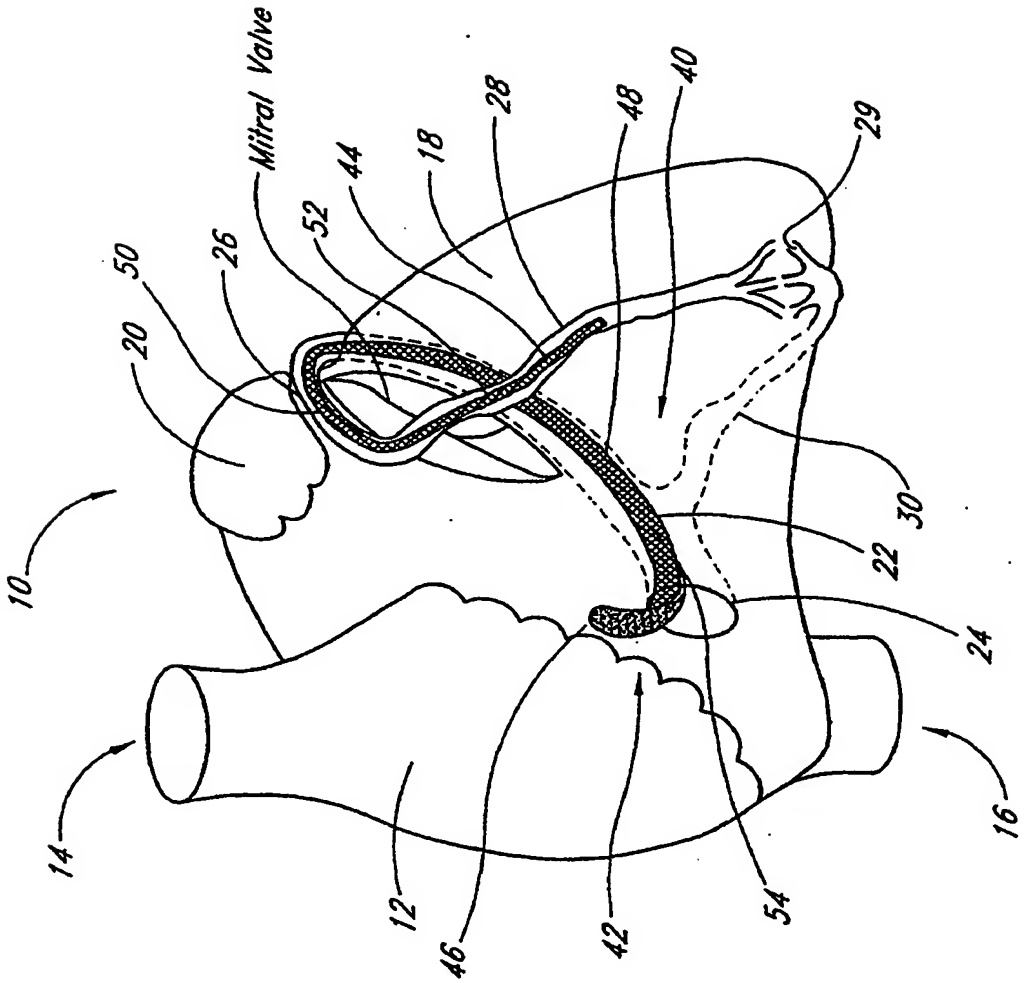
Mitral Valve
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FIG. 1

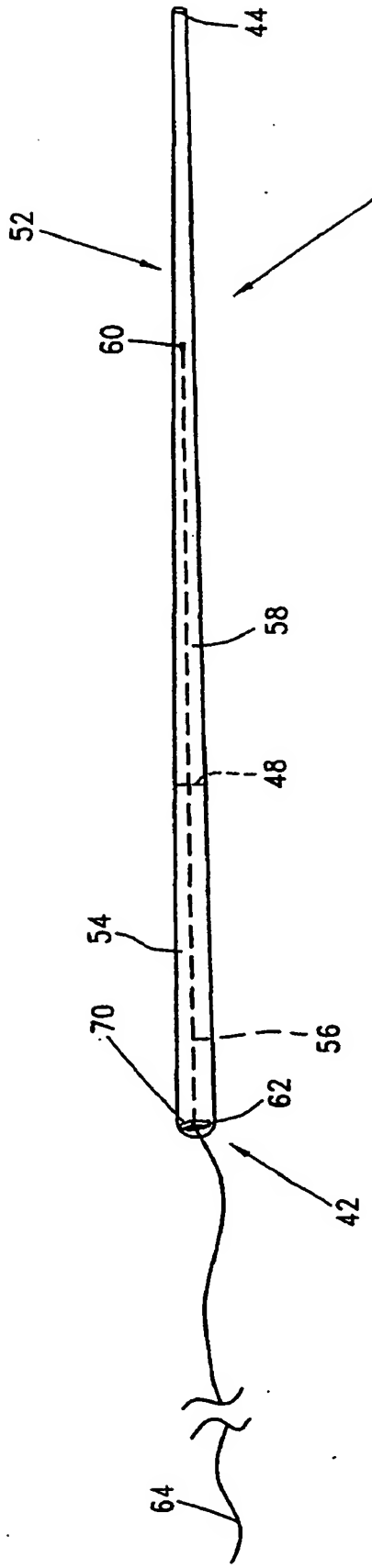

FIG. 2A

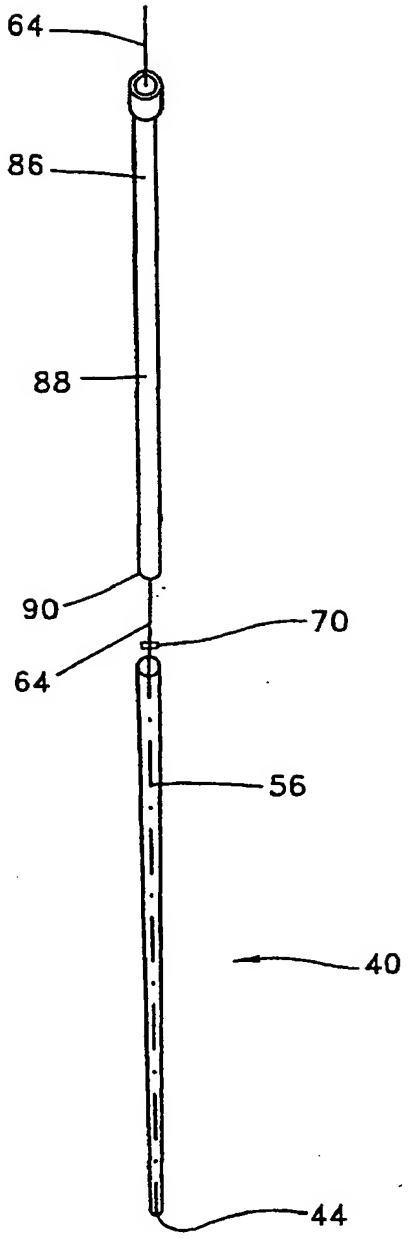

FIG. 4

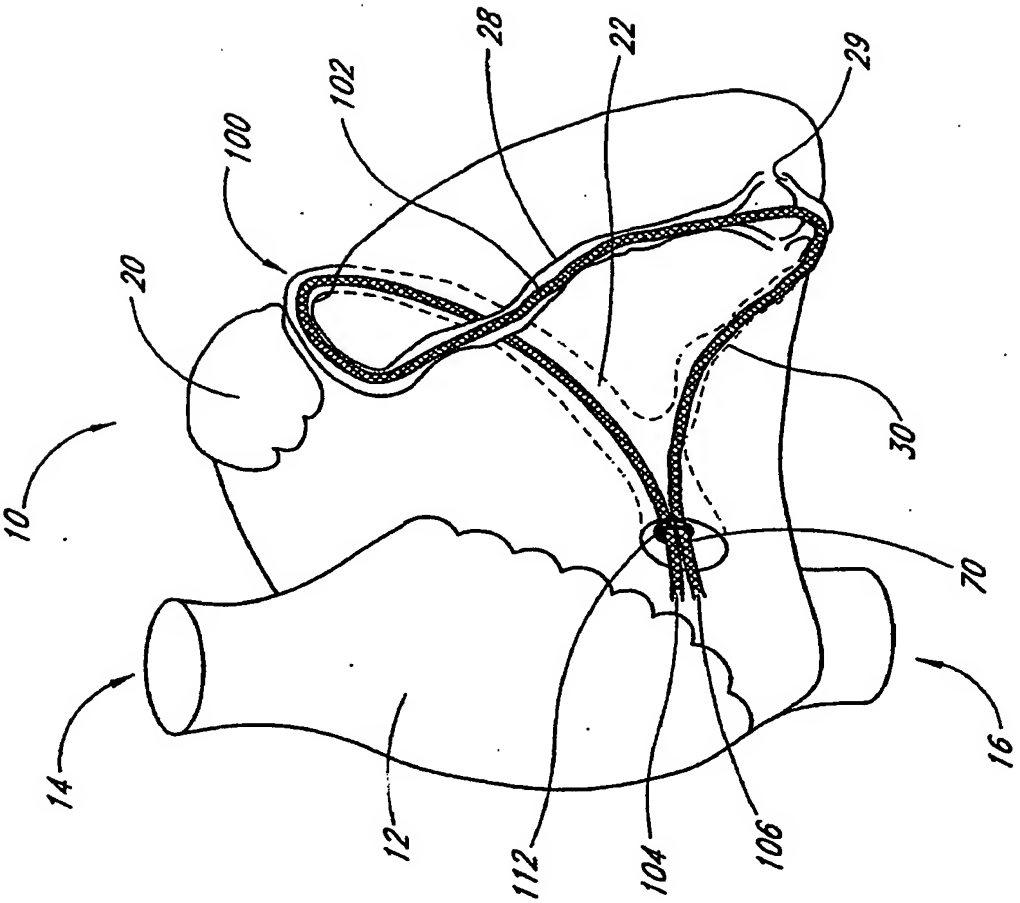

FIG. 6

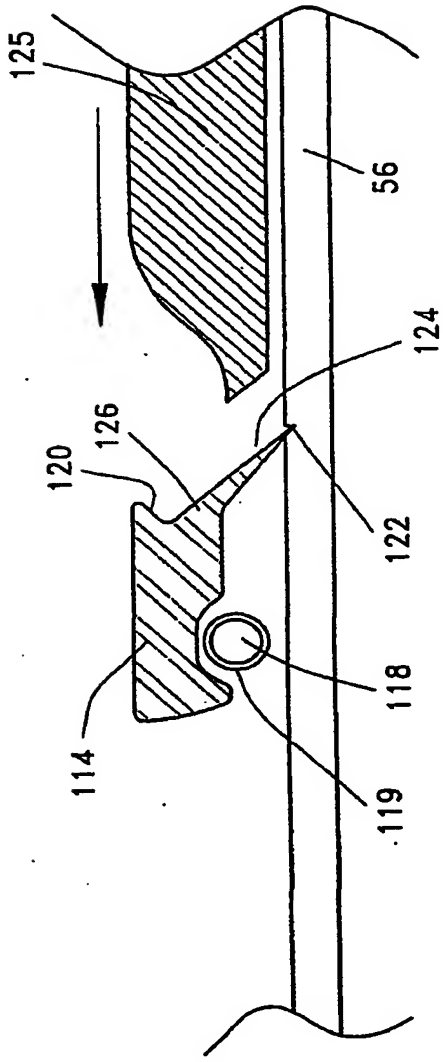

FIG. 8

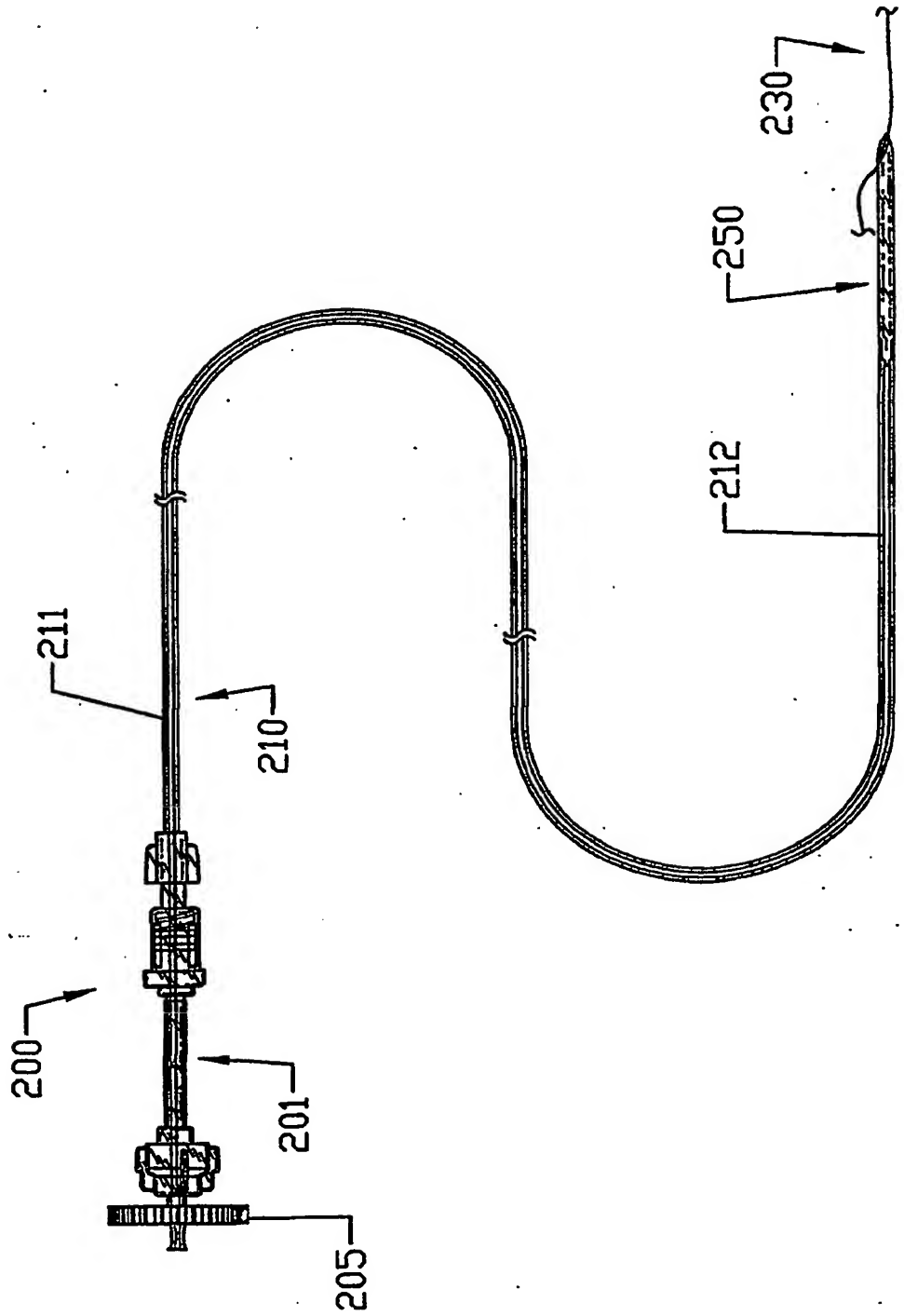

FIG. 10

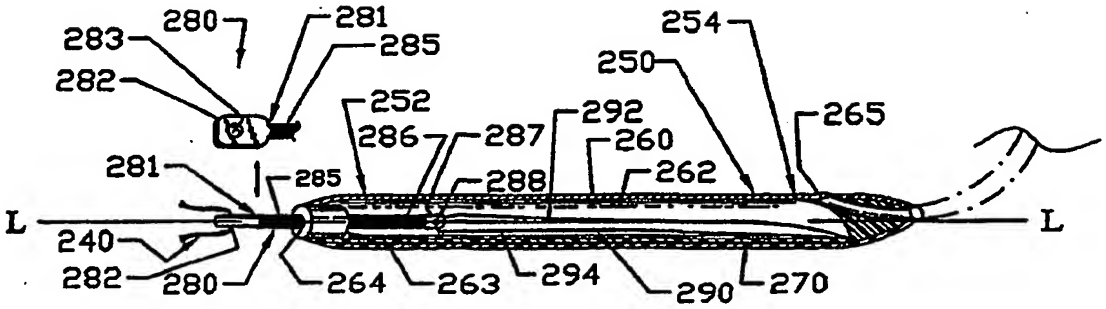

FIG. 13A

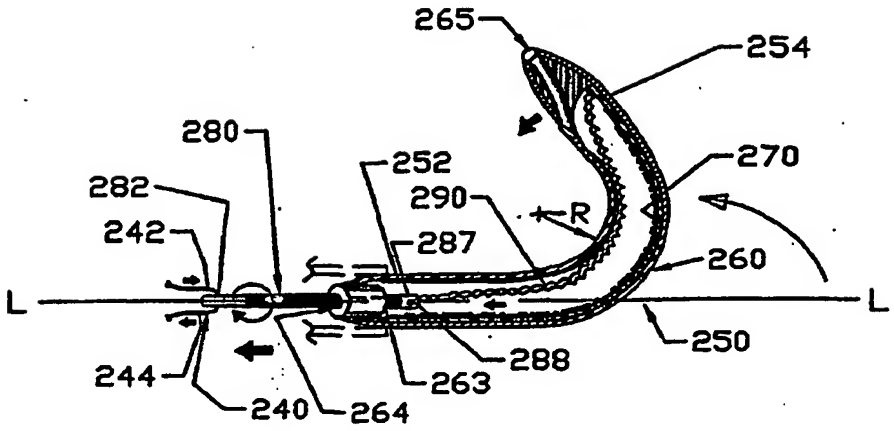

FIG. 13B

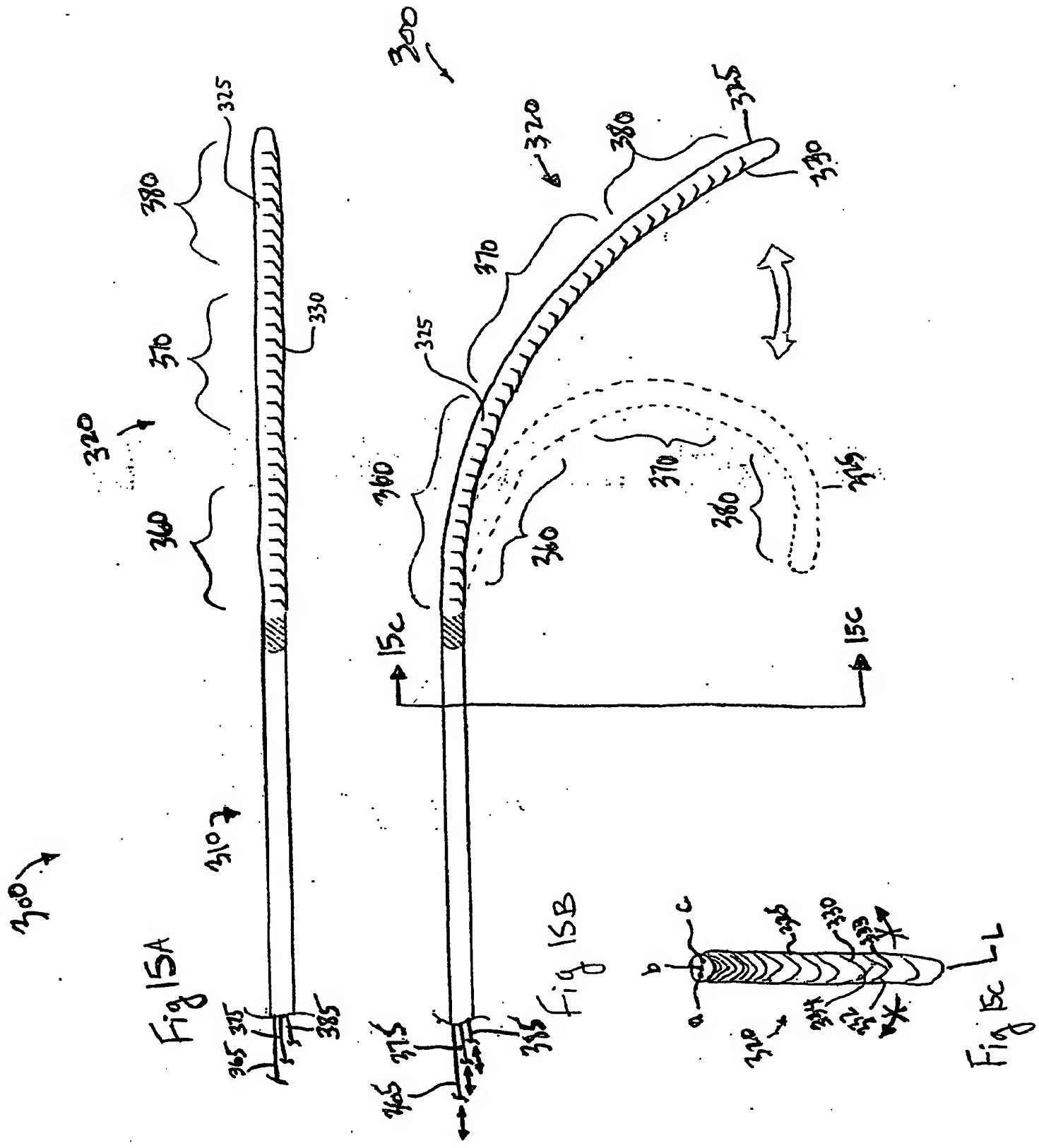

Fig 15A Fig 15B Fig 15C

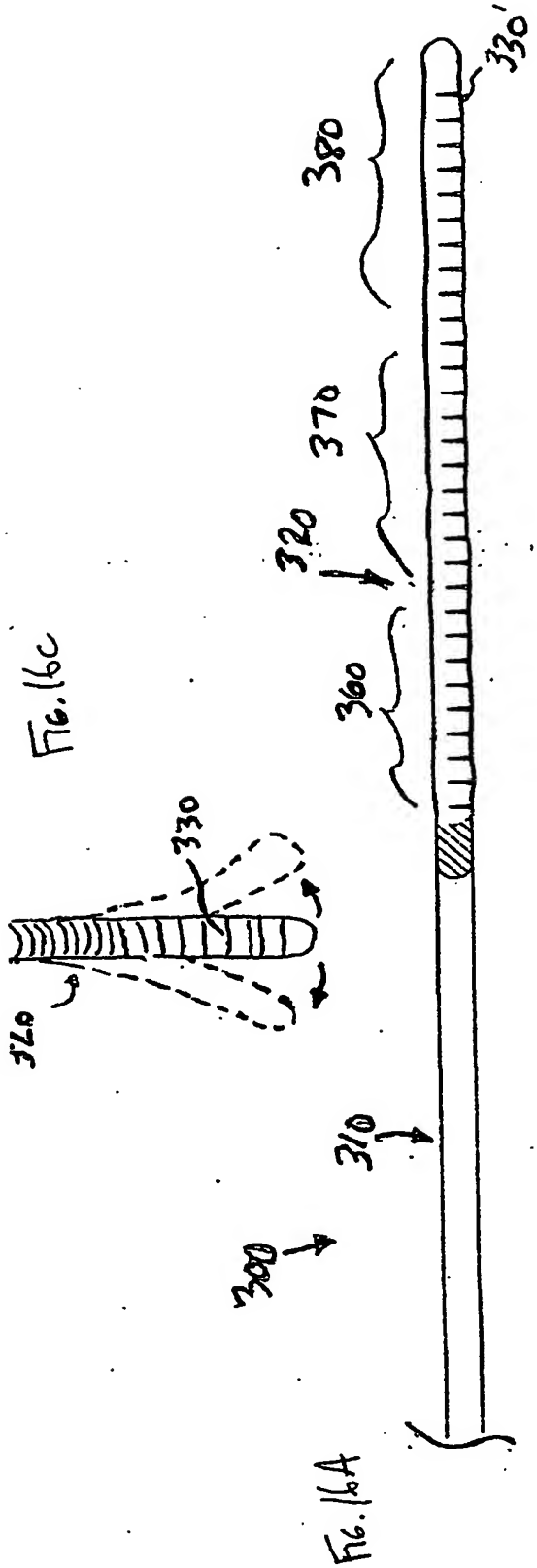

Fig. 16A

Fig. 16C

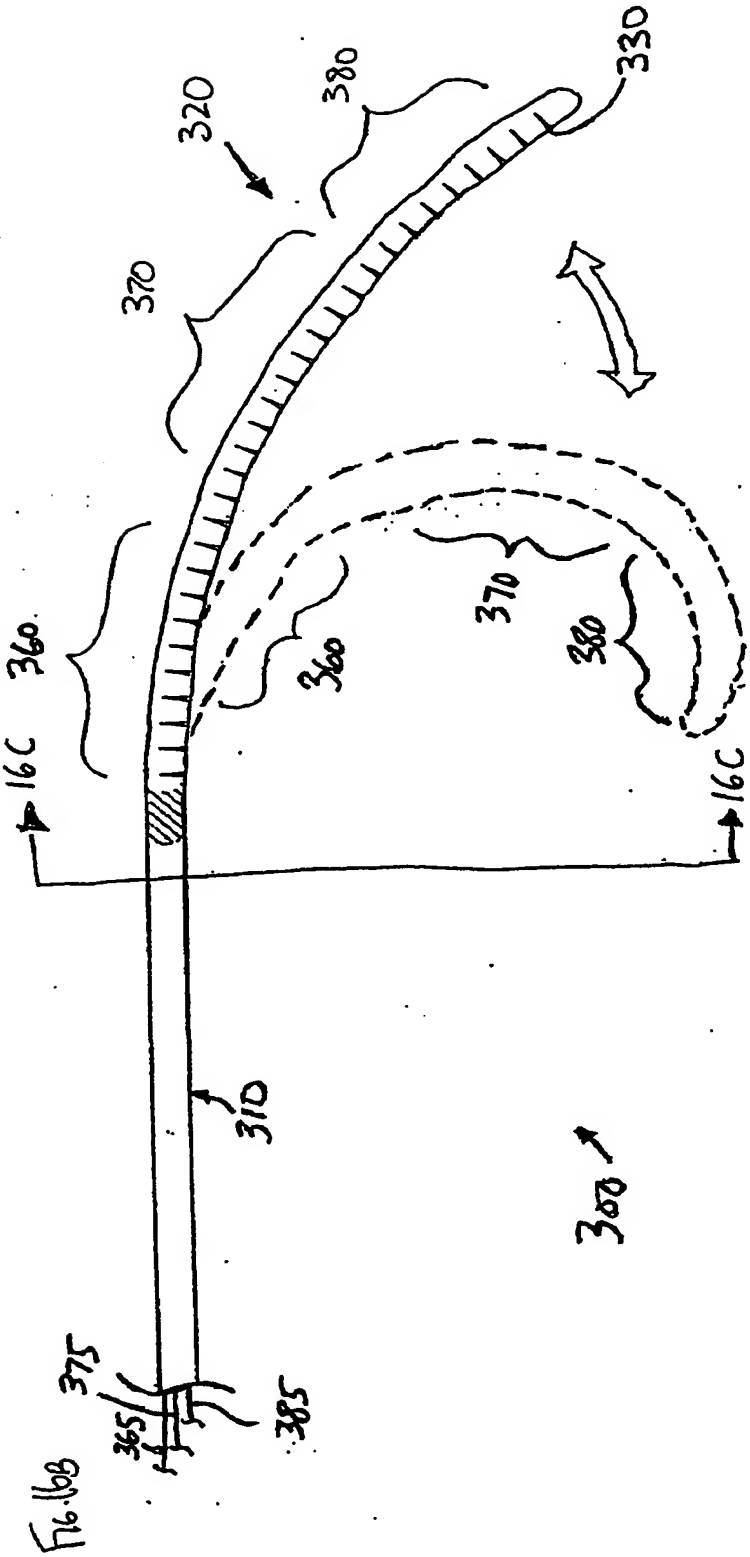

Fig. 16B

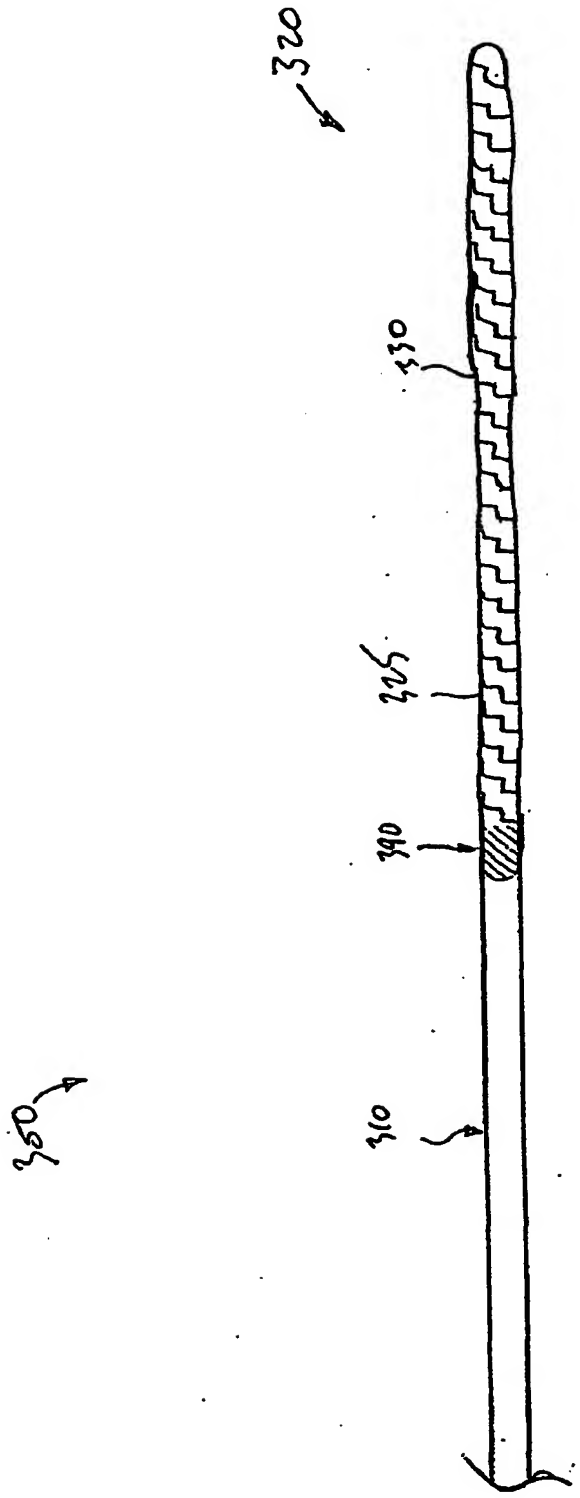

Fig 17A

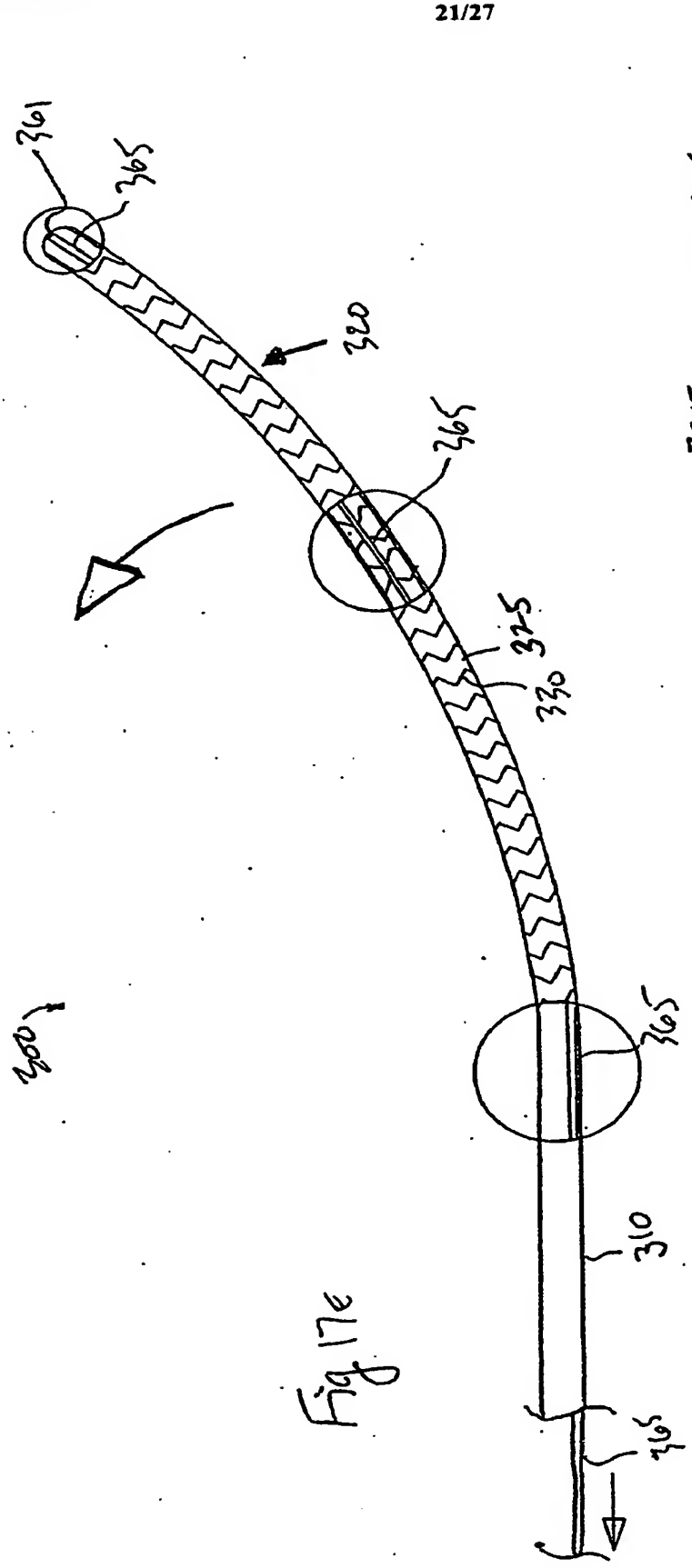

Fig 17E

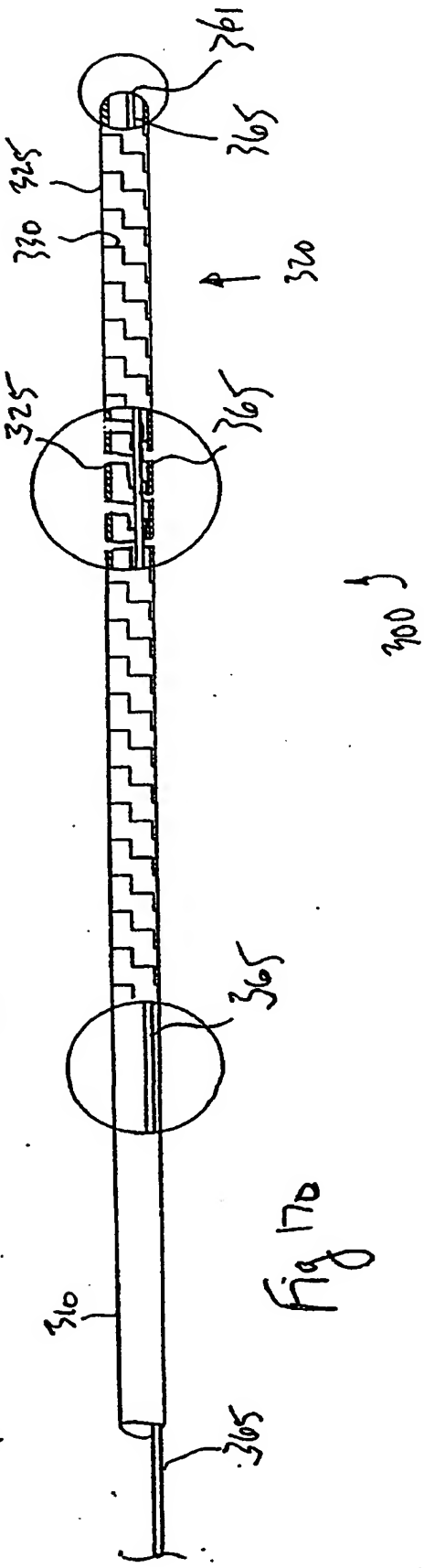

Fig 17D

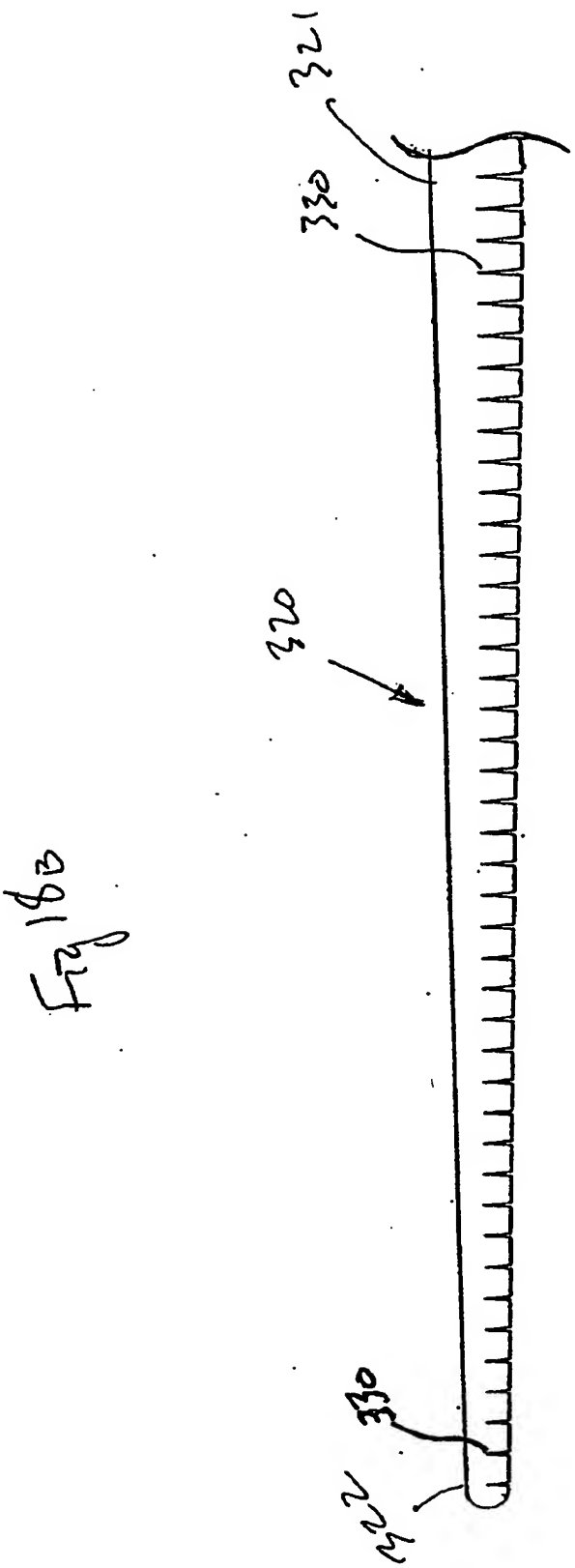

Fig 16B

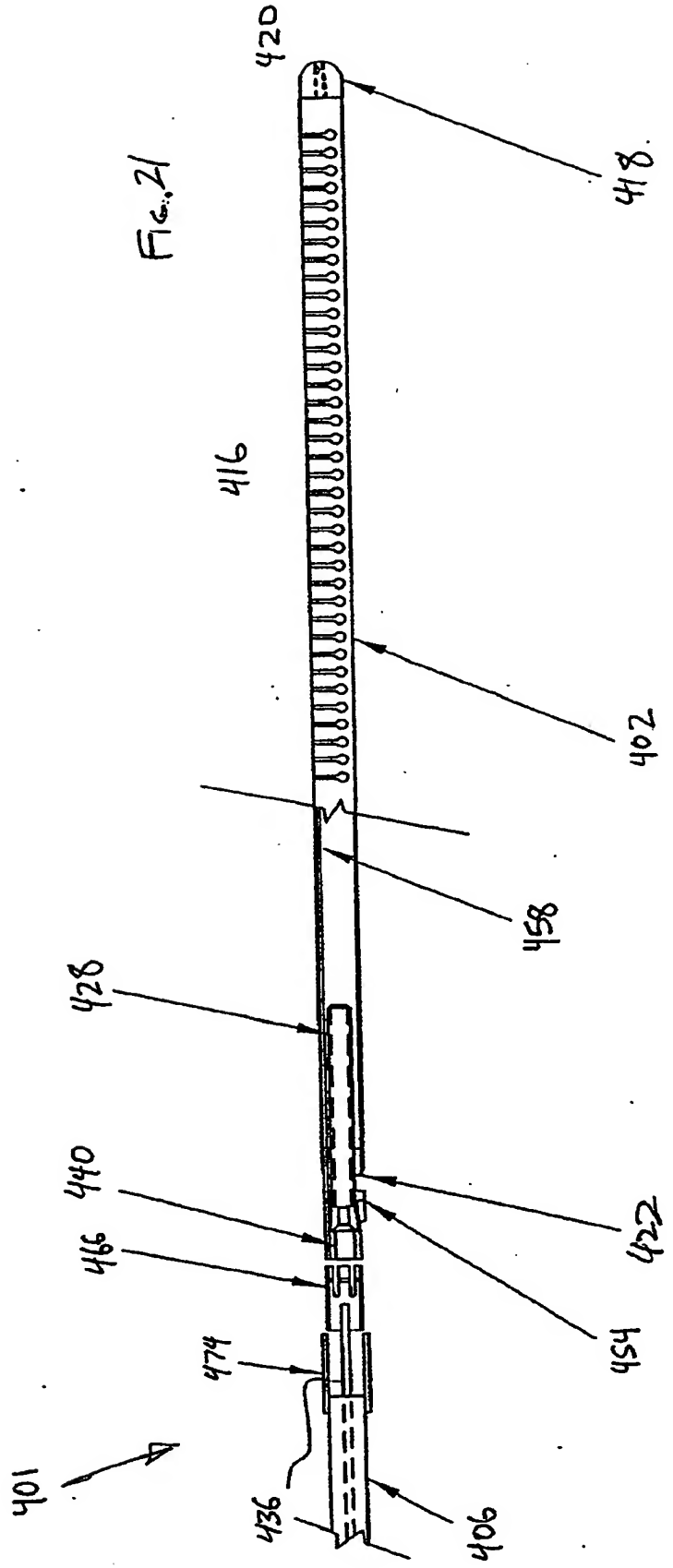
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FIG. 21

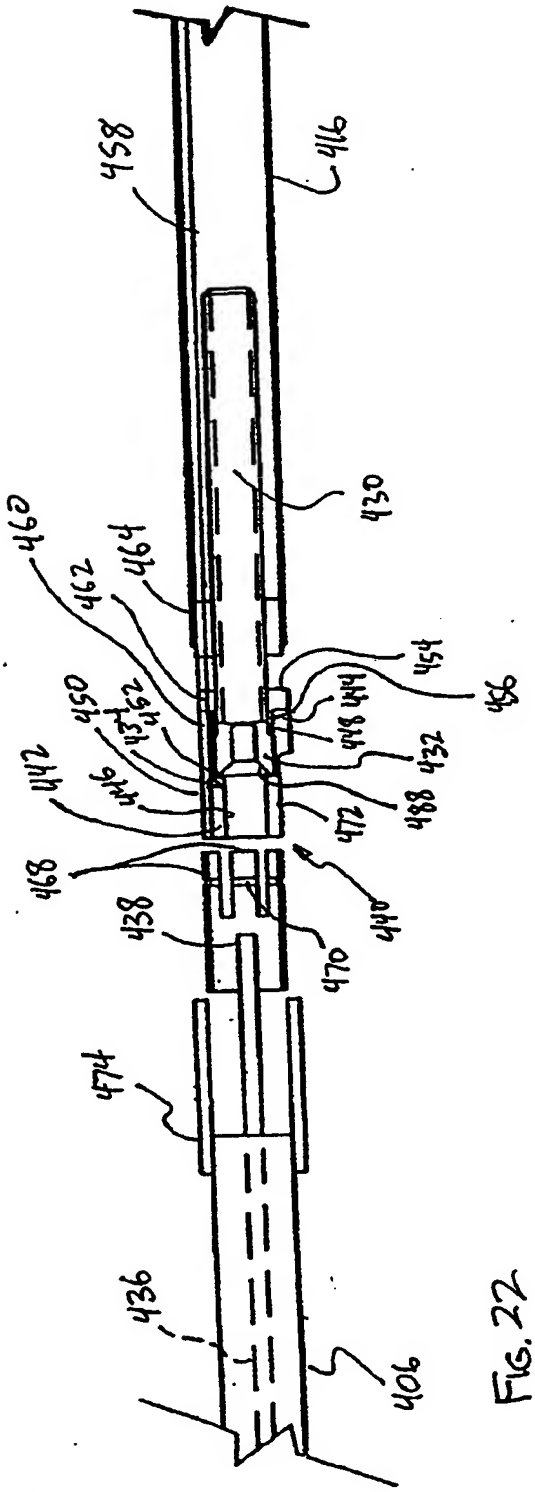
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FIG. 22

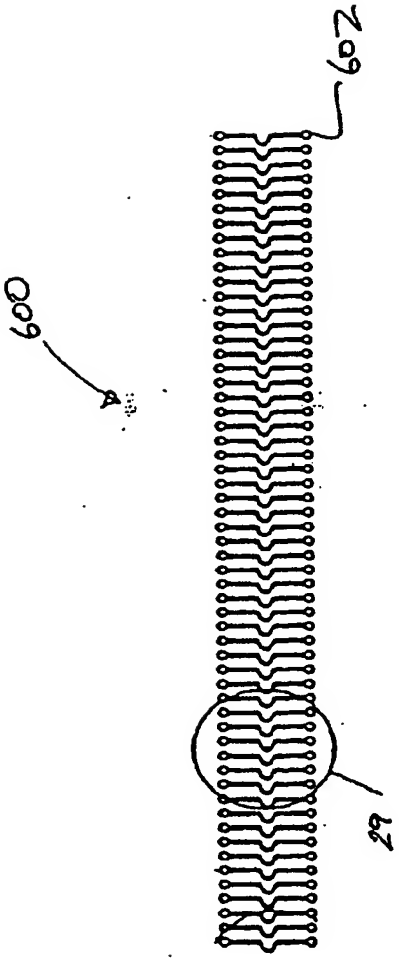

Fig. 28

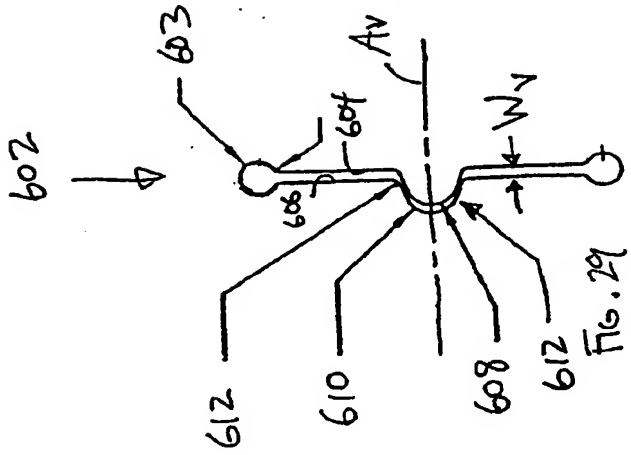

Fig. 29